

**COMMITTEE ON PESTICIDES, CHEMICAL
REGULATION & RIGHT-TO-KNOW COMMITTEE**

***TSCA REFORM LEGISLATION
UPDATE AND PRIMER***

TSCA AMENDMENTS OF 2016

JUNE 28, 2016

WELCOME & INTRODUCTIONS

Moderator: Larry Culleen, Partner, Arnold & Porter LLP

Honored Guest: Jim Jones, Assistant Administrator, US EPA

Featured Panelists:

Alex Dunn, Executive Director & General Counsel, Environmental Council of the States

Mike Walls, VP Regulatory & Technical Affairs, American Chemistry Council

Richard Denison, Lead Senior Scientist, Environmental Defense Fund

Ernie Rosenberg, President & CEO, American Cleaning Institute

Lynn Bergeson, Managing Partner, Bergeson & Campbell, P.C.

Keith Matthews, Counsel, Sidley Austin LLP

REVIEW OF MEETING AGENDA

Remarks of EPA Assistant Administrator (Jim Jones)

Tutorial on Significant Sections

- Section 4 – Testing (Lynn Bergeson)
- Section 5 – Manufacturing and New Uses (Lynn Bergeson)
- Section 6 – Prioritization, Risk Evaluation/Management (Richard Denison)
- Section 8 – Inventory (Keith Matthews)
- Section 14 – Confidentiality (Keith Matthews)
- Section 18 – State – Federal Relationship (Alex Dunn)
- Section 26 – Administration, Fees, Policies and Guidance (Mike Walls)

Round Up of Important Points of View

- Environmental Interest Groups (Richard Denison, EDF)
- State Agencies (Alex Dunn, ECOS)
- Manufacturers (Mike Walls, ACC)
- Processors and Formulators (Ernie Rosenberg, ACI)

Open Discussion and Q&A

STATUS OF TSCA AMENDMENTS

FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

- **House of Representatives voted 403 – 12; May 24**
- **Senate passed bill by unanimous consent; June 7**
- **Signed by President Obama on June 22, 2016**

TUTORIAL

§4. TESTING

Expands EPA authority to require development of information

- Authorizes administrative orders and consent agreements in addition to rule making
- Permits EPA to require testing needed for prioritization
- New authority does not require EPA findings
- May not be used to establish “a minimum information requirement of broader applicability”

New Section 4(h) concerns vertebrate animal testing and requires EPA to:

- Reduce and replace such testing to extent practicable, scientifically justified, and consistent with policies of diminished animal testing
- Develop, within 2 years of enactment, and implement a strategic plan to promote alternative test methods

TUTORIAL

§5. NEW CHEMICALS/SIGNIFICANT NEW USES

- Retains certain basic requirements
90-day review period, extensions permitted
- Requires EPA determination on all Notices
- Three alternative determinations:
 - NC/SNU presents an unreasonable risk
 - Available information is insufficient **or** NC/SNU may present unreasonable risk **or** NC/SNU chemical has substantial production and exposure, or
 - NC/SNU not likely to present unreasonable risk

TUTORIAL

§5. NEW CHEMICALS/SIGNIFICANT

NEW USES (CONT'D)

- **EPA required to regulate under 1 and 2**
- **Limits ability to regulate articles/category of articles compared to prior TSCA, but**
- **Requires EPA also to apply a SNU rule under 1 and 2 or “make public” a statement explaining its findings, the publication of which in the *Federal Register* is not a prerequisite to manufacturing or processing**

TUTORIAL

§6. PRIORITIZATION, RISK EVALUATION, RISK MANAGEMENT OF EXISTING CHEMICALS

- Adds prioritization
- Includes timelines
- Specifies minimum number of cases
- Prioritization applies risk-based screening process to designate high- versus low-priorities
 - High-priority: *May present* an unreasonable risk because of a *potential hazard* and a *potential exposure*
 - Low-priority: Does not meet this standard
- Where information is insufficient to support low-priority, default decision is high-priority
- Specifies high-priority categories

TUTORIAL

§6. PRIORITIZATION, RISK EVALUATION, AND RISK MANAGEMENT OF EXISTING CHEMICALS (CONT'D)

- Risk Evaluation process determines whether chemical *presents* an unreasonable risk
- Chemicals found to present unreasonable risk must proceed to EPA risk management action
- Determinations regarding low-priorities and substances that do not present an unreasonable risk can be subject to judicial challenge

TUTORIAL

§6. PRIORITIZATION, RISK EVALUATION, AND RISK MANAGEMENT OF EXISTING CHEMICALS (CONT'D)

- For chemicals that present an unreasonable risk, EPA is required to take timely risk management action
- TSCA's "least burdensome" language deleted; simplified procedural requirements
- EPA must consider/publish statement on certain cost-benefit aspects
- When EPA prohibits one or more uses, EPA also must consider availability of *technically and economically feasible alternatives*
- Allows for exemptions if certain requirements can be met
- Final §6 rules and associated risk evaluations can be subject to judicial review

TUTORIAL

INFORMATION GATHERING AND CBI

§8. Reporting and Retention of Information

- **Requires continued use of certain nomenclatures**
- **Includes Inventory “reset” process involving:**
 - Reporting rule to obtain information on *active chemicals*
 - Manufactured/imported/processed during previous 10-years
- EPA to designate chemicals as *active* or *inactive*
- Status of *inactive* chemicals can be changed by notice to EPA
- EPA to review and approve/deny CBI claims made for chemical identity

TUTORIAL

INFORMATION GATHERING AND CBI (CON'T)

§14. Confidential Information

Revises and replaces TSCA Section 14

- New section considers *information not protected from disclosure*, including that on:
 - Banned or phased-out chemicals, with certain limitations
 - Health and safety studies
- “does not authorize the disclosure of any information, including formulas (including molecular formulas (including molecular structures) of a chemical..., that discloses processes used...or, in the case of a mixture,... the portion of the mixture comprised by any of the chemical substances in the mixture”
- 10 year limitation on CBI protection, subject to renewals
- Requires assertion and substantiation of most CBI claims

TUTORIAL

§ 18. STATE-FEDERAL RELATIONSHIP

- Preemption was one of the most debated aspects of TSCA reform
- Grandfathers:
- States' actions taken before April 22, 2016
- Action taken pursuant to state laws in effect August 31, 2003 (e.g., Prop 65)
- After final EPA action, prohibits states from establishing or continuing to enforce statutes, regulations, etc., that would:
 - Duplicate information requirements under TSCA §§4, 5, or 6 actions
 - Prohibit or restrict a chemical after EPA has determined that a chemical does not present an unreasonable risk or issued a final §6(a) rule, or
 - Subject a chemical to the same notification of use already established in §5 SNU rule

TUTORIAL

§ 18. STATE-FEDERAL RELATIONSHIP

- **Exceptions: Past and future actions are not preempted when the state action:**
 - Is not a restriction/implements a reporting or other information obligation not otherwise required by TSCA or any other federal law
 - Is adopted under the authority of another federal law
 - Under certain circumstances, is adopted under a state law related to water quality, air quality, or waste management
 - Is identical to a requirement prescribed by EPA (with penalties no less stringent than available to EPA)
 - Relates to a low-priority chemical or to a new chemical

§ 18. STATE-FEDERAL RELATIONSHIP

Additional provisions:

- **Waivers:** Allows states to seek a waiver from preemption restrictions during or after EPA review
- **Note:** Preemption prohibits states from imposing new laws once EPA takes certain TSCA actions, such that a waiver granted may remain in effect only until such time as EPA publishes a §6(b) risk evaluation, after which:
 - Final preemption applies if EPA finds no unreasonable risk or,
 - If EPA finds unreasonable risk, states can act until the RM action is final
- **Savings:** Ensures that preemption does not affect state or federal common law rights and private remedies (e.g., tort actions)

TUTORIAL

§26. ADMINISTRATION AND FEES

- **Expands EPA's authority to collect fees to defray costs subject to certain limitations**
 - Applies to manufacturers and processors
 - Fee rule developed in consultation with industry
 - Fund and accountability provisions
- **Requires EPA to:**
 - Use the best available science and weight of evidence
 - Develop needed policies, procedures, and guidance (PP&G)
 - Establish Science Advisory Committee on Chemicals (SACC)

INDUSTRY PERSPECTIVE ON KEY MODIFICATIONS

- **Strengthened Preemption Provisions**
- **Scientific Standards**
- **Affirmative Determinations**

OPEN DISCUSSION

QUESTION & ANSWER SESSION